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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,551	11/27/2001	Jamie S. Henderson	498-269	8199

7590

06/01/2004

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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/994,551	Applicant(s) HENDERSON ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/9/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 14-17 and 21-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 13 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/21/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Species A in Paper Filed 4/12/04 is acknowledged. Claims 1-5, 12, 13 & 18-20 were elected as readable on invention I, Species A.

Applicant's election with traverse of the species set forth in Paper No. 3 is acknowledged. The traversal is on the ground(s) that the species D (figure 3) & E (figure 4) are searchable with Species A (figure 1), since figure 1 shows a ribbed structure and figures 3 & 4 show alternate cross-sections for the rib designs, and therefore, the rib structure search for figure 1 would also cover the structures of figures 3 & 4 without undue burden. Applicant requested that claims 1-13 & 18-20 be examined for invention I, species A, D & E. This is not found persuasive because the present application contains claims directed to patentably distinct species, which are different inventions. Regardless of the search, the law states that one invention per patent is allowed the restriction is proper. As stated in MPEP Section 806.04(f), claims are restricted to different species when one claim recites limitations in a first species that are not found in second species, while another claim recites limitations disclosed for only the second species and not the first. For example, in this case, Species A, figure 1, while reciting ribs this is a broad recitation, and species D (figure 3) and species E (figure 4) recite specific, and therefore distinct, structure of ribs. Therefore, it is clear that Species A and D & E are distinct from one another. To have properly traversed the restriction Applicant should have submitted evidence or identified

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evidence already of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions to be unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention(s).

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-11, 14-17 & 21-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention & Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in paper filed 4/9/04.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-5, 12, 13, 18 & 19 are rejected under 35 U.S.C. 102(b) as anticipated by Shors (4,969,896). Shors discloses a graft 10 having a tubular body 20, defining a lumen 50, an inner (i.e. interior) surface 30 and an outer (i.e. exterior) surface 40 of the tubular body. Shors also disposes a plurality of ribs 60 spaced apart from one another, and extending both radially outward from and longitudinally along the body. The graft further comprises a wrap (i.e. sleeve) 70 that is tubular and is attached to a portion of the ribs and thereby the ribs are "formed unitarily" with the wrap. Shors discloses that the material used to make the ribs may be silicone rubber, polyethylene, polypropylene, polyurethane or other elastomeric biocompatible materials. With respect to claim 12 specifically, the ribs may be adhered to the surface of the wrap, therefore there will inherently be a sealant material adjacent to the ribs by bonding.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shors ('896) in view of Kalis (5,609,624). Shors discloses the invention substantially as claimed, see rejection supra. Shors, however, fails to disclose specifically that the ribs are made of expanded polytetrafluoroethylene (ePTFE). Shors does disclose that the material used to make the ribs may be polyethylene, or other elastomeric biocompatible materials.

Kalis discloses a vascular graft that is tubular, having ribs, wherein the rib structures are ePTFE. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shors to make the ribs of ePTFE as taught by Kalis, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stenoien et al. Discloses a vascular graft having a ribbed or non-smooth surface.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 27th, 2004

Patricia M Bianco
Primary Examiner
Art Unit 3762


PATRICIA BIANCO
PRIMARY EXAMINER